Message

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Subject: OCSPP News for February 26, 2021

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- Public Employees for Environmental Responsibility (PEER) 02/24; EPA Scientists Sound Alarm on Chemical Assessments
- The National Law Review (Hunton Andrews Kurth) 02/25; Advocacy Groups and Plaintiffs' Experts Launch Two Challenges to EPA's Asbestos Risk Evaluation – Are EPA Settlements Possible?
- The National Law Review (Squire Patton Blogs) 02/26; Significant Activity Follows US EPA's TSCA Asbestos Risk Evaluation
- Web Wire 02/25; The EPA Releases Supplement to its Draft Risk Evaluation for 1,4-Dioxane

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FDA Lists PFAS in Cosmetics as Advocates Plan Legislative Push

Pat Rizzuto, Bloomberg Law

https://news.bloomberglaw.com/environment-and-energy/fda-lists-pfas-in-cosmetics-as-advocates-plan-legislative-push

Teflon chemical among those in cosmetics, FDA says

Advocates want California-modeled law made national

Chemical safety advocates who are lobbying for restrictions on "forever chemicals" in cosmetics say a new FDA website shows the need for the U.S. to adopt California's model on addressing PFAS in personal products.

The Food and Drug Administration last week posted, for the first time, information about per- or polyfluoroalkyl substances, or PFAS, found in body lotions, nail polish, shaving cream, foundation, mascara, and other personal care products. The agency highlighted missing safety data, but made no other statement about the safety or risks of products containing PFAS.

"PFAS in cosmetic products is an area of increasing interest for many consumers," FDA spokeswoman Kimberly DiFonzo said.

The agency's new page provides "consumers with labeling information on common PFAS used as ingredients in certain cosmetic products, the research to date, and FDA's continued efforts to monitor the scientific literature on developments to help us better understand this emerging area of science," she said.

But the agency's "very innocuous, non-committal, somewhat vague statement" illustrates why the Campaign for Safe Cosmetics will lobby Rep. Frank Pallone, Jr. (D-N.J.), Rep. Jan Schakowsky (D-Ill.), and Sen. Dianne Feinstein (D-Calif.), Janet Nudelman, the campaign's director, said.

The three lawmakers plan to reintroduce legislation strengthening the FDA's authority over cosmetics and banning at least some PFAS from them.

California Laws

The campaign wants the lawmakers to include in the bills two California laws from last year— one that banned 24 chemical ingredients, including 13 PFAS, from cosmetics, and one requiring manufacturers by 2022 to disclose flavor and fragrance ingredients in cosmetics, Nudelman said.

A trade group for cosmetics makers defended their members' products in a statement that did not address possible legislation.

"The beauty industry is confident in the safety of the ingredients used in cosmetics," said Jay M. Ansell, a vice president with the Personal Care Products Council, which represents some 600 ingredient and product manufacturers and companies such as L'Oréal S.A., Revlon, Inc., and the Procter & Gamble Co.

The council supported the FDA's effort to educate consumers about ingredients in the products they buy and its plan to track PFAS research, Ansell said in an email. It also has encouraged its members to participate in the agency's Voluntary Cosmetic Registration Program that allowed it to identify PFAS ingredients, he said.

Legislation Returning

Cosmetics makers used about 21 types of PFAS as ingredients in 2019 to 2020, according to information reported by manufacturers, the FDA said. These include a Teflon chemical called polytetrafluoroethylene

(PTFE), perfluorooctyl triethoxysilane, perfluorononyl dimethicone, perfluorodecalin, and perfluorohexane, the agency said.

Companies add the chemicals to prevent powders from caking, help makeup stay on, and deliver oxygen to skin, according to UL LLC's Prospector, which provides technical information about chemicals to product developers.

The problem is that the 1938 law giving the FDA authority over cosmetics didn't give it the power or mandate to oversee safety, said Nudelman and Scott Faber, senior vice president of government affairs for the Environmental Working Group, an advocacy group that has long focused on PFAS.

The law says cosmetics must be safe, but the FDA doesn't review them ahead of time, according to agency information. Instead, the industry-funded Cosmetic Ingredient Review panel examines ingredients safety. FDA participates, but doesn't vote on the panel's conclusions, it said.

"That's why Congress needs to give FDA more authority," Faber said.

'Long Overdue'
Pallone, chairman of the House Energy and Commerce Committee, plans to reintroduce his Cosmetic Safety Enhancement Act later this year; Schakowsky, who chairs...

General Mills 'working with suppliers' to phase out phthalates
Leigh Stringer, Chemical Watch
https://chemicalwatch.com/222148/general-mills-working-with-suppliers-to-phase-out-phthalates

US consumer foods manufacturer, General Mills, is working with its suppliers to eliminate phthalates that may be present in the packaging materials and food processing equipment used by the dairy industry to produce its Annie's macaroni and cheese products.

Phthalates are used in food contact materials (FCMs) as plasticisers, binders, coating agents, defoamers, gasket closures and slimicide agents.

In a communication to NGOs, seen by Chemical Watch, General Mills said it is finalising plans to "ensure effectiveness of its commitment", including direct supplier and industry outreach.

The company said the focus will remain on the packaging materials and food processing equipment that produces the cheese and cheese powder in its Annie's macaroni and cheese products, but the work with suppliers will have "broader impacts".

It added that it is working with trade organisations to move this effort beyond any one product or company, as it can be "best addressed by the dairy industry directly".

"Our suppliers provide other ingredients to us and work with other customers, and changes they make for us will impact others," it said.

The company declined to comment further on the details of its work with its suppliers.

In December last year, the company communicated its effort to eliminate phthalates in a set of FAQs it published in 2017. This was in response to a report by US NGO Defend Our Health – formerly the Environmental Health Strategy Center – claiming that its tests found phthalates in dairy ingredients used to

make store-bought macaroni and cheese.

The report claimed that 29 of the 30 analysed samples from various brands sold on the US market tested positive for phthalates, mainly DEHP, DEP, DIBP and DBP. Samples included two of Annie's Homegrown varieties of macaroni and cheese powder.

Across all 29 products, the total concentration of phthalates ranged from 34 to 218ppb.

In the last five years, NGOs and industry group the Flexible Vinyl Alliance have separately petitioned the FDA to pull its approval of 26 phthalates historically used in food packaging because "their use has been permanently abandoned".

Despite industry and NGOs reaching consensus on these substances, they remain opposed in whether the four phthalates still used in food contact applications are safe – DEHP, DCHP, DINP and DIDP.

In the EU, the European Food Safety Authority (Efsa) sets a Total Daily Intake (TDI) of 5ppb for four phthalates – DEHP, DINP, DBP and BBP – and 15ppb for DIDP.

General Mills said its macaroni and cheese products have been tested and "we know any trace of phthalates are below the Efsa standard".

Market leadership
"We applaud General Mills for its market leadership in asking its suppliers to eliminate these toxic chemicals from food processing equipment," said Brandon Moore, US national campaign director for Defend Our Health.

The NGO has now called on General Mills to announce a public timeline to achieve its phthalates phase out goal, as well as expand its commitment to other Annie's products and its other brands.

Defend Our Health and Canadian NGO Environmental Defence are also calling on other processed food companies such as Kraft and Nestlé to "match General Mills' leadership commitment to toxic-free food".

"Although a growing number of food companies have ended the use of phthalates in food packaging, General Mills is the first to publicly commit to clean up its supply chain to require suppliers to eliminate phthalates in food processing equipment," they said.

Food processing equipment, rather than packaging, is thought to be the major source of phthalates that enter food, they said.

"Phthalates have been found in 100% of conveyor belts and 80% of plastic tubing used for food processing, according to testing by scientists from the US FDA," they added.

Nestlé told Chemical Watch that it implemented a global, mandatory standard on phthalates in 2018, which states that their use as plasticisers and...

Tighter VOC limits loom in New York for consumer products
Kelly Franklin, Chemical Watch
https://chemicalwatch.com/222278/tighter-voc-limits-loom-in-new-york-for-consumer-products

A variety of consumer products will face more stringent volatile organic compound (VOC) limits in New York from 2022, after changes to existing regulations took effect earlier this month.

Amendments to the state's 'Part 235' consumer products rule will bring in new requirements for adhesives, some automotive cleaners and solvents, disinfectants, household floor and furniture cleaners, paint thinners and some hair care products, among other categories.

The Department of Environmental Conservation's updated rule took effect on 11 February. It establishes VOC content limits for nine new product categories and lowers these for ten existing ones.

New product categories include:

aromatic compound;
artist's solvent or thinner;
automotive windshield cleaner;
high temperature coating;
industrial maintenance coating;
paint thinner;
sanitiser;
temporary hair colour; and
zinc rich primer.
Meanwhile, revised requirements apply to the following:

contact adhesive;
electronic cleaner;
fabric protectant;
floor polish or wax;
general purpose cleaner;
general purpose degreaser;
lubricant;
multipurpose solvent;
oven or grill cleaner, and
rubber or vinyl protectant.
The updated VOC limits take effect on 1 January 2022.

New York's changes largely align with the Ozone Transport Commission 'phase IV' model rule for consumer products. The OTC is a coalition of northeast states that develop regional solutions for ground-level ozone problems, which includes the development of 'model rules' that individual states can adopt.

Delaware, Connecticut, Maryland and Rhode Island are all following the same phase IV model rule, according to an adoption status update the OTC published on 18 February.

California, meanwhile, is in the process of adopting changes to its consumer products rules, in a move that would preserve its role of maintaining the tightest VOC regulations in the nation. The California Air Resources Board (CARB) has a public hearing scheduled for 25 March to consider their adoption.

AIM coatings rule
New York's update to its consumer products rule follows its adoption of tougher requirements for architectural and industrial maintenance (AIM) coatings last year.

The new VOC limits for AIM coatings had been slated to take effect by early next year. However, the state issued an enforcement discretion letter on 30 December allowing an additional 12 months to comply, in acknowledgment of "the impact on the actions and operations of New York state businesses and the regulated community due to the Covid emergency."

The AIM coatings requirements are now scheduled to take effect on 1 January 2022 under this enforcement discretion policy.

Researchers call for lifecycle studies for insulation flame retardant PolyFR

Dr. Emma Davies, Chemical Watch

https://chemicalwatch.com/221835/researchers-call-for-lifecycle-studies-for-insulation-flame-retardant-polyfr

There is an urgent need for environmental fate and toxicity data on the modern insulation flame retardant PolyFR, according to a team from the Green Science Policy Institute, US and the University of Toronto.

The polymeric flame retardant, a copolymer of polystyrene and brominated polybutadiene, is added to foam insulation materials as a replacement for hexabromocyclododecane (HBCD). PolyFR is regarded as a safer alternative because its large size and high molecular weight make it less likely to migrate out of products and move through the environment.

Led by Miriam Diamond from the University of Toronto, the researchers analysed the lifecycle of expanded and extruded polystyrene foams to highlight when PolyFR degradation products could feasibly be released to the environment. Their flow chart covers PolyFR and foam production, followed by foam installation, use and disposal.

The team's analysis suggests a serious lack of information. There is a need for a more rigorous toxicity and hazard assessment of PolyFR in foams under "realistic scenarios" across the lifecycle, focusing particularly on early and end-of-life stages, it says.

"There is remarkably little research on PolyFR, given its high-volume use and the possibility of it breaking down into monomers and escaping into the environment," co-author Arlene Blum, executive director of the Green Science Policy Institute, told Chemical Watch.

HBCD is a substance of very high concern (SVHC) under REACH and is also banned under the Stockholm Convention. However, decades of use has left tonnes of the chemical trapped in buildings, resulting in ongoing exposure during renovation or demolition, the researchers write in the journal Environmental Science & Technology (ES&T).

"We need to avoid repeating similar mistakes by obtaining the information needed to ensure PolyFR is an informed substitution rather than a regrettable one," they say.

Although academic studies on the substance are limited, the team quotes a 2019 study by an aquatic ecology group at the University of Duisberg-Essen in Germany, led by Bernd Sures.

The study suggested that UV light or prolonged heat exposure could lead to a variety of degradation products, "which might have potentially adverse environmental effects and an increased mobility compared with the mother polymer", according to another ES&T article.

Professor Sures agrees that "we need more research to evaluate possible interactions of all types of new flame retardants and their possible degradation products with the environment along the entire lifecycle of the products." His group is still working on PolyFR.

"For several years we have tried to encourage other researchers, but studying polymers is challenging," Dr Blum told Chemical Watch.

"One of our main motivations for this viewpoint is to encourage other researchers to study PolyFR. Another is to make the point that more information is needed about polymers, especially those that are used at high-volume. For both flame retardants and PFAS, polymers are being increasingly produced without adequate health and environmental information," said Dr Blum.

Chemical regulations do not typically call for the same level of scrutiny for polymers as for other substances. However, the EU is currently discussing proposals to include their registration under REACH.

California Regulators Back 'Class' PFAS Approach, Raising Pressure On EPA
Curt Barry, Inside EPA
https://insideepa.com/daily-news/california-regulators-back-class-pfas-approach-raising-pressure-epa?utm_source=dlvr.it&utm_medium=twitter

The push from environmentalists and some states to regulate per- and polyfluoroalkyl substances (PFAS) as a single class could get a boost from a new article by California Department of Toxic Substances Control (DTSC) staffers that sets out their basis for regulating PFAS as a class under the state's Safer Consumer Products (SCP) green chemistry program.

"Based on the currently available science, we have concluded that it is both ineffective and impractical to regulate this complex class of chemicals with a piecemeal approach and have, therefore, initiated regulatory action to list certain consumer products containing any PFAS as Priority Products under the SCP regulations," reads the commentary by four DTSC staffers in the February issue of Environmental Health Perspectives.

In the commentary's introduction, the authors say they are presenting "the rationale adopted by [DTSC] for regulating PFAS as a class in certain consumer products."

Specifically, the four DTSC staffers -- Simona Andreea Balan, Vivek Chander Mathrani, Dennis Fengmao Guo, and André Maurice Algazi -- lay out two core reasons for regulating certain consumer products if they contain any PFAS chemical.

First, "all PFAS, or their degradation, reaction, or metabolism products, display at least one common hazard trait according to the California Code of Regulations, namely environmental persistence," they state.

Second, "certain key PFAS that are the degradation, reaction or metabolism products, or impurities of nearly all other PFAS display additional hazard traits, including toxicity; are widespread in the environment, humans, and biota; and will continue to cause adverse impacts for as long as any PFAS continue to be used."

As a result, they write, "In the case of PFAS, we believe that all members of the class have a potential for significant and widespread adverse impacts due to their extremely high environmental persistence, coupled with growing evidence for human and ecological health hazards for the impurities, metabolites, and degradation products of the subset commonly used in consumer products."

Regulating PFAS "as a class is thus logical, necessary, and forward-thinking," they add. "This technical position may be helpful to other regulatory agencies in comprehensively addressing this large class of chemicals with common hazard traits."

The DTSC's public argument for class-based PFAS rules comes as a group of nine states that includes California is defending its newly released model legislation to ban PFAS and phthalates in product packaging.

The Toxics in Packaging Clearinghouse (TPCH), which includes California, Connecticut, Iowa, Minnesota, New Hampshire, New Jersey, New York, Rhode Island and Washington, on Feb. 16 formally updated its model bill for packaging restrictions to bar both chemicals as unified classes, rejecting industry arguments that the approach would have "perverse" consequences.

Several industry groups and individual firms argued against that strategy in 2020 comments on a then-proposed version of the bill.

Most prominently, the American Chemistry Council in its comments said treating PFAS as a class would lead to "perverse economic consequences" and also "flawed regulations -- and chemical assessments based on these regulations -- and may create public confusion, cause unwarranted alarm, and product de-selection. All of which serves to further erode public confidence in existing chemical management programs."

Both the TPCH bill and DTSC's article increase pressure from environmentalists and some state and federal lawmakers for EPA to regulate PFAS as a class under the Toxic Substances Control Act (TSCA). Doing so would allow the agency to quickly block most uses of the substances in consumer products through the law's new-chemicals program.

Last year, a group of researchers largely funded by environmentalists urged policymakers to regulate thousands of PFAS as one large group and to bar non-essential uses, arguing...

Environmentalists Fire Back At EPA Claim Methylene Chloride Suit Is Moot
Maria Hegstad, Inside TSCA
https://insideepa.com/tsca-news/environmentalists-fire-back-epa-claim-methylene-chloride-suit-moot

Environmentalists are already firing back at EPA's claim that it mooted their suit seeking strict limits on commercial use of methylene chloride (MC) in paint-strippers when it began developing a TSCA risk management rule for those products, saying the current process is too slow and that the agency has implicitly admitted its prior delays were unlawful.

Petitioners in Labor Council for Latin American Advancement et al. v. EPA argue in a Feb. 24 letter that EPA's latest filing in the case, where it says it is already developing a rule for commercial paint-strippers and thus there is no point to litigation on the subject, concedes that it was wrong not to take that step in 2019.

That is because the agency's pending Toxic Substances Control Act (TSCA) rulemaking is based on a June 2020 evaluation of methylene chloride that maintains findings on the chemical's commercial uses in paint-strippers from a 2014 risk assessment -- even though when EPA issued the 2019 rule at issue in the suit, it claimed not to have enough information to decide whether commercial uses should be banned.

"Critically, EPA's risk evaluation does not contain new information on the risks from commercial use of methylene chloride paint strippers. Instead, EPA evaluated those uses based on analyses from its 2014 methylene chloride risk assessment, which EPA excerpted, verbatim, in a risk evaluation appendix," the plaintiffs write to the U.S. Court of Appeals for the 2nd Circuit.

"EPA's conclusion that the risk evaluation supports a finding of unreasonable risk concedes that the 2014 risk assessment does as well, refuting EPA's claim that it lacked sufficient information in its March 2019 rule."

And they argue that the TSCA risk management process, under which EPA has until mid-2022 to finalize a rule, is no substitute for the speedier regulatory action they are seeking.

"Far from 'doing precisely what Petitioners ask the Court to order,' an unnecessary, second rulemaking locks in the harmful delay that Petitioners commenced this suit to avoid. The Court should instead remand the MC Rule and order EPA to immediately finalize the commercial use regulations that TSCA requires based on the 2014 risk assessment," the letter says.

In the case, environmentalists and labor groups are arguing that the agency unlawfully opted to ban only consumer uses of methylene chloride paint strippers in its 2019 rule, rather than also limiting commercial uses as many commenters sought and as the Obama EPA included in a proposed version of the rule. Both elements of the proposal were based on the 2014 assessment.

Oral argument in the suit is slated for March 4 and will also include claims from industry that the ban on consumer uses is too stringent and unlawfully affects small businesses.

But EPA argued in a Feb. 23 letter to the court that after completing the TSCA evaluation last summer, it now faces a statutory deadline to regulate the unreasonable risks that it identified, including commercial use of paint strippers containing the solvent. Thus, there is no reason to consider the merits of environmental and labor groups' arguments that EPA should have acted sooner, the agency concludes.

"EPA determined that commercial use of methylene chloride in paint and coating removal presents unreasonable risk. . . . As a result, EPA is proceeding to do precisely what Petitioners ask the Court to order EPA to do: issue a risk management rule for the commercial use at issue here," the letter says.

TSCA Process

But the petitioners counter in their new filing that the normal TSCA process -- despite its strict deadlines for EPA to propose risk management within one year of the final evaluation's publication and to finalize the rule within two years -- is not fast enough, given the acute and lethal risks methylene chloride poses.

"EPA's decision to exclude commercial uses from that rule despite their unreasonable risks is final agency action, notwithstanding EPA's plan to begin...

Chlorine Institute seeks to intervene in asbestos evaluation suit
N/A, Inside TSCA
https://insideepa.com/tsca-takes/chlorine-institute-seeks-intervene-asbestos-evaluation-suit

The Chlorine Institute has asked the U.S. Court of Appeals for the 9th Circuit to allow it to intervene in environmentalists' challenge to EPA's recently finalized TSCA evaluation of the risks posed by chrysotile asbestos, signaling that it will oppose any action in the case that could "adversely affect" importation and use of the substance.

In a Feb. 25 motion to intervene, the association argues that while petitioners in Asbestos Disease Awareness Organization (ADAO) et al. v. EPA are "ambiguous" in their petition to the 9th Circuit "as to what relief Petitioners may seek herein," the case could result in new limits on import or use of chrysotile asbestos used to make chlorine.

"[T]o the extent that Petitioners seek remedies herein that may adversely affect the importation and distribution in commerce of chrysotile asbestos . . . it follows that the Institute's member companies who use chrysotile asbestos for the manufacture of chlorine may be adversely affected by such remedies, depending on the precise remedies Petitioners seek," the motion says.

"Accordingly, the Institute has standing, and it should be allowed to intervene herein to protect its interests and those of its members."

The filing follows ADAO's Jan. 26 filing of a petition for review with the 9th Circuit, over EPA's final evaluation "determining the risks of certain conditions of use of chrysotile asbestos fibers but declining to consider the risks of other asbestos fibers, conditions of use, health effects and pathways of exposure that impact public health."

If the 9th Circuit approves the Chlorine Institute's request, it would become a defendant in the case -- allowing it to defend any elements of the Trump-era Toxic Substances Control Act (TSCA) evaluation that the Biden EPA abandons, and giving it a voice in any settlement negotiations.

The 9th Circuit petition is limited to the findings of EPA's Dec. 30 evaluation, which narrowly focused on chrysotile asbestos and left analysis of other fiber types as well as legacy uses for a later "supplemental" evaluation. The Trump administration announced alongside release of the chrysotile evaluation that it planned to take comment on the scope of the next study "mid-year 2021," but the Biden EPA has not stated how it intends to proceed.

The Dec. 30 evaluation finds that 16 of 32 uses of chrysotile asbestos pose unreasonable risks to workers, consumers or bystanders, triggering a one-year deadline under TSCA to propose risk management rules to mitigate those risks. If ADAO and its allies prevail, EPA could be forced to reexamine the 16 uses it found did not warrant regulation.

The Chlorine Institute explains in its filing -- as its representatives testified last year when Congress was considering an ultimately unsuccessful bill to ban asbestos -- that in "the United States, there are 10 large chlorine production facilities that use chrysotile asbestos in the process, which account for 38 percent of installed capacity in the United States."

Further, the trade group says, chlorine is used in a number of critical applications, including municipal drinking water disinfection and the production of household bleach and polyvinyl chloride (PVC). It is also used to make "88 percent of pharmaceuticals produced in the United States."

The association notes that chrysotile asbestos "is the only form of asbestos that is used for chlorine production in the United States."

In addition to the current suit, ADAO and its co-petitioners also warned the Biden administration that they intend to sue separately over what they say is the agency's failure to fully assess risks posed by asbestos, including discontinued "legacy" uses.

The groups sent a Jan. 26 notice of intent to sue under TSCA section 20, which allows citizen groups to file suit against the agency when it fails to complete a "non-discretionary duty" mandated by the law.

Specifically, the potential suit outlined in the notice of intent would force the agency to
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How a poor school groundskeeper took on Monsanto and won
Roland Klose, St. Louis Post-Dispatch
https://www.stltoday.com/entertainment/books-and-literature/reviews/how-a-poor-school-groundskeeper-took-on-monsanto-and-won/article_33e3bd16-bfa6-5276-b424-9d8d2a5b2390.html?utm_medium=social&utm_source=twitter&utm_campaign=user-share

If a company hides information that suggests its top money-making product is unsafe, keeps adverse findings from regulators, employs ghostwriters to gin up favorable scientific studies and media coverage, funds front groups in an attempt to discredit critics, fails to provide warnings to consumers, and, according to jurors who reviewed a mountain of evidence, is responsible for serious illnesses and death, how would you hold the people responsible to account?

If the company were Monsanto, you couldn't.

Monsanto — once one of the marquee corporate names in St. Louis — is now gone, gobbled up in 2018 for a whopping $63 billion.

Bayer AG paid a premium and Monsanto shareholders made a bundle, just as lawsuits alleging a link between Monsanto's Roundup weed killer and non-Hodgkin's lymphoma were beginning to heat up. Did hubris account for Bayer's failure to heed warning signs? Or did Bayer bank on the long game, knowing that in America most everything can be resolved for a price? Whatever the answer, Bayer is now putting the finishing touches on settlements to resolve more than 100,000 Roundup-related lawsuits, as well as likely future litigation.

But Dewayne "Lee" Johnson, the very first plaintiff to win a judgment against Monsanto, no longer has to wait.

In August 2018, a California jury awarded Johnson, a former school groundskeeper, $289 million after finding that his contact with Roundup — one time, the weed killer soaked his body when a hose broke — contributed to his horrifying cancer. Monsanto, the jury agreed, should have provided a label warning of the potential health hazard.

The verdict made international headlines, but after a series of appeals, the amount Johnson recently received is a fraction of the initial verdict.

Veteran investigative journalist Carey Gillam tells Johnson's story in her latest book, "The Monsanto Papers," a fast-paced, engaging account of how Monsanto and Bayer's fortunes changed dramatically in such a short span of time.

She introduces us to Johnson, who after struggling for many years, landed steady work and was building a solid life with his wife and two young kids in Vallejo, California. But by 2014, he was fighting a virulent form of cancer that left him covered with painful skin lesions — and struggled to find out why.

She takes us to Virginia, where a firm led by a successful husband-wife team of trial lawyers was looking for its next big moneymaking lawsuit. It found it in March 2015 when the International Agency for Research on Cancer, the cancer research arm of the World Health Organization, identified glyphosate, the key ingredient in Roundup, as a probable carcinogen.

She describes how the IARC scientific report "was a plaintiffs' attorney's dream," setting off a scramble to find people with a potentially strong case against Monsanto, the leading maker of glyphosate-based weed killer. Discovery in the lawsuits uncovered what looked a lot like corporate fraud and deceit as well as suppression of scientific evidence by key regulators, including the U.S. Environmental Protection Agency.

Monsanto's campaign against critics only intensified after the IARC findings were released, and Gillam, a former Reuters reporter whose work has appeared in the Post-Dispatch, even found herself among its targets. Internal Monsanto documents show how the company planned to attack her work and suppress coverage of her first book, "Whitewash," published in...

Hit hard by Roundup and dicamba payouts, Bayer posts billions in losses

Bryce Gray, St. Louis Post-Dispatch

https://www.stltoday.com/business/local/hit-hard-by-roundup-and-dicamba-payouts-bayer-posts-billions-in-losses/article_b920a01b-f1cb-5a05-a1fc-d569b70d7aa6.html

Agribusiness giant Bayer on Thursday posted billions of dollars in losses, driven largely by payouts to settle allegations that the company's weedkillers damaged crops and hurt people.

The company attributed payouts of more than 20.4 billion euros — about $25 billion — to its crop science business, including the former Monsanto Co. in Creve Coeur, according to year-end financial results released Thursday. The sum included settlements related to marquee Monsanto weedkillers Roundup and dicamba.

The costs pushed Bayer losses to 10.5 billion euros, or about $12.8 billion. The company made 4 billion euros in 2019.

Annual sales fell 5% or 2.1 billion euros to 41.4 billion euros. Fourth quarter sales fell 755 million euros or 7% over the same period in the prior year to 10 billion euros; profit tumbled 1.1 billion euros or 78% to 308 million euros.

Crop science sales in the fourth quarter fell 400 million euros or 10% to less than 4.2 billion euros over the same period a year prior. Annual sales slipped 1 billion euros or 5% to about 18.8 billion euros.

Bayer bought Monsanto in 2018 for $63 billion, and still houses its global seeds and traits headquarters there. Monsanto developed some of the products for which Bayer has assumed liability in legal battles.

The company has faced a wave of lawsuits alleging that glyphosate, the active ingredient in Roundup, causes cancer. Last year, Bayer reached an agreement to pay up to $10.9 billion to settle thousands of glyphosate cases. Earlier this month, the company announced an additional $2 billion to resolve future Roundup claims.

Bayer also agreed last year to pay $400 million to settle claims involving dicamba — a weedkilling chemical that has ignited years of controversy over allegations it drifts off-target and damages other crops. Since the release of seed varieties that can tolerate dicamba herbicides sprayed over the top of them, farmers have reported millions of acres of related crop damage in the U.S., and a rising tide of lawsuits has emerged in court.

Bayer executives said earnings were hurt by the temporary suspension of sales for its Xtendimax weedkiller containing dicamba, after another lawsuit triggered a federal court ruling that banned the product. It is now back on shelves, and has gained new registration.

An analyst suggested on an earnings call Thursday that Bayer consider splitting its crop science division from other components of its business, "to reduce some of the uncertainty around glyphosate" — and suggested that the idea might arise at upcoming investor events.

But Bayer Chairman Werner Baumann insisted that the company is committed to keeping its three-pronged family of crop science, pharmaceuticals and consumer health businesses intact.

"There is no consideration of divesting of any of those businesses," he said.

Bayer leaders said that, aside from things like litigation-related payouts, the company's operational performance was strong, and showed promise for the future — particularly in areas like crop science, thanks to the current market share and growth potential for products ranging from soybean seed systems to digital agriculture tools...

Bayer's plan for settling future Roundup cancer claims faces broad opposition

Carey Gillam, U.S. Right to Know

https://usrtk.org/monsanto-roundup-trial-tracker/bayers-plan-for-settling-future-roundup-litigation-faces-broad-opposition/

Dozens of U.S. law firms have formed a coalition to fight a new $2 billion settlement proposal by Monsanto owner Bayer AG that aims to contain the company's ongoing liability related to claims that Roundup herbicides cause a type of cancer known as non-Hodgkin lymphoma (NHL).

The settlement is designed to compensate people who have been exposed to Roundup products and either already have NHL or may develop NHL in the future, but who have not yet taken steps to file a lawsuit.

The small group of lawyers who put the plan together with Bayer say it will "save lives" and provide substantial benefits to people who believe they developed cancer from exposure to the company's herbicide products.

But many lawyers criticizing the plan say if it is approved it would set a dangerous precedent for other types of litigation involving large numbers of people injured by the products or practices of powerful corporations.

"This is not the direction we want the civil justice system to go," said attorney Gerald Singleton, whose firm has joined with more than 60 other law firms to oppose Bayer's plan. "There is no scenario under which this is good for plaintiffs."

Bayer's settlement plan was filed with the U.S. District Court for the Northern District of California on Feb. 3, and must be approved by U.S. District Judge Vince Chhabria in order to become effective. A prior settlement plan submitted last year was scorned by Chhabria and then withdrawn. The judge has been overseeing the federal multidistrict Roundup litigation involving thousands of plaintiffs from around the United States.

Responses to the settlement plan are due March 3 and a hearing on the matter is set for March 31.

A key concern is that current Roundup users who may develop cancer and want to sue in the future will automatically be subject to terms of the class settlement unless they officially opt out of the settlement within a specific time period. One of the terms they would be subject to would bar them from seeking punitive damages in any future lawsuit.

Those terms and others laid out are wholly unfair to farm workers and others who are expected to develop cancer in the future from exposure to the company's herbicide products, according to Singleton. The plan benefits Bayer and provides "blood money" to the four law firms that worked with Bayer to design the plan, he said.

Those firms working with Bayer to draft and administer the plan would receive a proposed $170 million if the plan takes effect.

Elizabeth Cabraser, one of the lawyers who crafted the new proposed settlement, said the criticism is not a fair description of the settlement. In truth, she said, the plan "provides significant and urgently-needed outreach, education, healthcare access, and compensation benefits" for people who have been exposed to Monsanto's Roundup herbicides but have not yet developed non-Hodgkin lymphoma (NHL).

"We seek approval of this settlement because it will save lives and enhance quality of life through early diagnosis, assist people… inform them and raise public awareness about the link between Roundup and NHL…" she said.

A spokesman for Bayer did not respond to a request for comment.

The new proposed settlement is aimed at future cases and is separate from the $11 billion Bayer has earmarked to settle existing U.S. Roundup cancer claims. The people impacted by the class settlement proposal are only individuals who have been exposed to Roundup but are not yet in litigation and have taken no steps toward any litigation.

Bayer has been struggling to figure out how to put an end to the Roundup cancer litigation since buying Monsanto in 2018. The company lost all three trials held to date and lost the early rounds of appeals seeking to overturn the trial losses.

Juries in each of the trials found not only that Monsanto's glyphosate-based herbicides cause cancer but also that Monsanto spent decades hiding the risks.

Though the proposed settlement states that it...

EPA's Disinfectant Policies Face Test Over Claim Of 'Bureaucratic Panic'
Diana DiGangi, Inside TSCA
https://insideepa.com/tsca-news/epa-s-disinfectant-policies-face-test-over-claim-bureaucratic-panic

A federal district court is weighing whether to address a hand-wipe maker's novel claim that EPA overstepped its authority to regulate disinfectants as it scrambled to respond to the COVID-19 pandemic -- a claim the agency says is not ripe for review as it has taken no formal action targeting the manufacturer.

In Feb. 17 filing with the U.S. District Court for the Southern District of New York, Tzumi Innovations says EPA's wave of Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) enforcement actions targeting disinfectant products during the COVID-19 pandemic amounts to "bureaucratic panic" over a wave of new entries to that market and urges the court to impose limits on the agency's authority.

But EPA is countering that Tzumi v. EPA, which the company filed to block any FIFRA enforcement action, is premature and says until it issues a FIFRA stop sale, use or removal order (SSURO) against the company itself, the manufacturer has no cause for a suit.

The agency says in a Feb. 24 memo that while it has warned Tzumi of a potential SSURO against its "Wipe-Out!" line of hand wipes, neither that warning nor a separate advisory letter "satisfy either prong" of the Supreme Court's test for a judicially reviewable "final agency action."

"The letter was tentative or interlocutory in nature, rather than a final enforcement action, and it determined no rights or obligations from which legal consequences will flow," EPA argues.

However, if the court rejects that argument it could set the stage for a ruling on the merits of Tzumi's claims that could curtail EPA's discretion to take action against manufacturers it claims are selling disinfectants without proper FIFRA registration, which has been a top priority for the agency's COVID-19 response under both the Trump and Biden administrations.

In its Feb. 17 memorandum, Tzumi accuses EPA of acting out of "bureaucratic panic" in response to COVID-19. "The pandemic was a new, unprecedented circumstance [which] led to a flood of greedy, opportunistic interlopers into the previously stable market for antimicrobial wipes. . . . The EPA does not know these newcomers or trust them, and it is 'overwhelmed' and 'inundated' by their number.

"To cope with the situation," Tzumi argues, "EPA has started handed out threatening Advisory Letters left and

right in order to intimidate some of the new entrants into withdrawing their product while it decides what to do about those that remain."

It says the threatened SSURO it faces from EPA Region 2 is part of that pattern and asks the district court to block any such order at least until the agency gives Tzumi an administrative hearing on its claims that it has only marketed the Wipe-Out! line for use on human skin -- which EPA has no authority to regulate under FIFRA.

EPA's Feb. 24 memorandum does not directly counter that argument and instead says the suit should be rejected on procedural grounds because none of its communications with Tzumi so far can pass the Supreme Court's test for "final action" subject to judicial review.

Under the high court's precedent in Bennett v. Spear, only actions that "mark the 'consummation' of the agency's decision-making process" and "by which 'rights or obligations have been determined,' or from which 'legal consequences will flow,'" can be challenged in court.

But Tzumi says it has sustained financial harm from the Region 2 threats, and that a recent SSURO against Amazon filed by Region 10 also limited sales of its products.

'Final Action'

Tzumi says that after EPA Region 2 told it that the agency could target it with a SSURO, and sent a written advisory letter, the company faced $10 million in lost or cancelled sales from three "major Tzumi customers."

And it says that the agency has effectively ordered it to stop selling Wipe-Out! products on penalty of FIFRA enforcement.

"An agency demand to cease and desist, or face enforcement action, is a final agency action. EPA's request left Plaintiff...

Richard E. Engler, Ph.D. and Jeffery T. Morris, Ph.D. Publish "Why the US EPA can, and should, evaluate the risk-reducing role a new chemical may play if allowed on the market," in Chemical Watch
N/A, Bergeson & Campbell Blogs
http://www.tscablog.com/entry/richard-e.-engler-ph.d.-and-jeffery-t.-morris-ph.d.-publish-why-the-us-epa

In the 21st century, we take as given a continuous stream of new and better products. From electronics to building materials to transportation solutions, the flow of new and better products and applications seems unending. New chemical substances play a fundamental role in creating those products and making existing products better. If the pipeline of new chemicals were closed off, the flow of new products and applications would slow to a trickle and eventually dry up. Modern life as we know it would not exist without the continued invention, production and use of new chemicals.

In the US, all new chemicals must be reviewed by the US EPA before they can enter commerce. The agency looks at new chemicals to determine whether their manufacturing, processing and use would adversely affect people or the environment. If the EPA identifies risks that it determines to be unreasonable, then it either prohibits use of the chemical, or requires restrictions on the chemical to control for risks. Since the 1970s, tens of thousands of chemicals have come through the EPA for review and have been allowed into US commerce.

In this article, Richard E. Engler, Ph.D. and Jeffery T. Morris, Ph.D. write that more robust consideration of a new chemical's potential to prevent pollution and lower risks could help achieve the right balance between

safety and innovation. The full article is available at https://chemicalwatch.com/220164/guest-column-why-the-us-epa-can-and-should-evaluate-the-risk-reducing-role-a-new-chemical-may-play-if-allowed-on-the-market (subscription required).

EPA Scientists Sound Alarm on Chemical Assessments
Kirsten Stade, Public Employees for Environmental Responsibility (PEER)
https://www.peer.org/epa-scientists-sound-alarm-on-chemical-assessments/?eType=EmailBlastContent&eId=0c167d78-9b3a-4c87-8a2d-8bdcd348ade2

Washington, DC — Scientists inside the U.S. Environmental Protection Agency who conduct evaluations of chemicals' harmful effects have issued a stinging vote of no confidence in their program leaders in a new federal employee survey. These negative survey results coincide with mounting reports of malfeasance inside EPA's chemical assessment programs, according to Public Employees for Environmental Responsibility (PEER).

The release of the annual Federal Employee Viewpoint Survey for 2020 conducted by the U.S. Office of Personnel Management contains disturbing answers from EPA specialists, particularly from its Office of Pollution Prevention and Toxics (OPPT), and its Risk Assessment Division (RAD) which reviews toxicity of new and existing chemicals. Noteworthy results include:

"I can disclose a suspected violation of any law, rule or regulation without fear of reprisal."

EPA: 20% negative
OPPT: 43% negative
RAD: 56.1% negative (highest of any division in OPPT)

"My organization's senior leaders maintain high standards of honesty and integrity."

EPA: 28.1% negative
OPPT: 60.4% negative
RAD: 64.6% negative

"Considering everything, how satisfied are you with your organization?"

EPA: 19.3% negative
OPPT: 53.8% negative
RAD: 58.2% negative

"It should be of grave concern that more than half the EPA chemists and other specialists working on crucial public health concerns do not feel free to report problems or flag violations," stated PEER Executive Director Tim Whitehouse, a former EPA enforcement attorney, noting the scientists register strong support for first line supervisors but disdain for senior management. "Not only are these morale ratings bad but they have been getting steadily worse."

These survey results follow on the heels of a scathing National Academies report faulting how these same EPA units evaluate the health risks of chemical exposures. The Biden-led EPA has embraced this report, but it is not clear what reforms will be implemented.

"EPA's new leadership will have its hands full righting this sinking ship," added Whitehouse, noting that

scientist complaints point to senior civil service managers, as well as political appointees. "Something is rotten in EPA and these survey results help identify a key cluster of bad apple managers."

Advocacy Groups and Plaintiffs' Experts Launch Two Challenges to EPA's Asbestos Risk Evaluation – Are EPA Settlements Possible?
Alexandra B. Cunningham, Matthew Z. Leopold, Gregory R. Wall, and Elizabeth Reese, The National Law Review (Hunton Andrews Kurth)
https://www.natlawreview.com/article/advocacy-groups-and-plaintiffs-experts-launch-two-challenges-to-epa-s-asbestos-risk

On January 26, 2021, a coalition of advocacy groups and prominent asbestos plaintiffs' experts launched two challenges to "Part 1" of the asbestos risk evaluation recently released by the United States Environmental Protection Agency (EPA). EPA concluded in Part 1 that 16 of the 32 "conditions of use" analyzed pose an "unreasonable risk" to human health, but advocacy groups have criticized EPA for only addressing risks associated with chrysotile asbestos and excluding review of other fiber types. Now, those groups have teamed up on a pair of legal challenges that could force EPA to revisit its Part 1 asbestos risk evaluation, which could delay risk management regulations.

First, the coalition filed a Petition for Review in the United States Court of Appeals for the Ninth Circuit seeking review of EPA's conclusions about asbestos and the comprehensiveness of its analysis. One of the Petition's chief complaints is that EPA "determin[ed] the risks of certain conditions of use of chrysotile asbestos fibers but declin[ed] to consider the risk of other asbestos fibers, conditions of use, health effects and pathways of exposure that impact public health."

Second, the coalition issued a Notice of Intent to Sue (NOI) under the Toxic Substances Control Act (TSCA) § 20(a)(2). The NOI alleges that EPA failed to perform a non-discretionary duty because (1) it did not complete the entire asbestos risk evaluation by June 19, 2020; and (2) the final risk evaluation failed to address the use and disposal of "legacy" asbestos (uses of asbestos that are not "ongoing," but may still pose a risk to consumers, such as asbestos in insulation).

While the coalition appears to have alleged valid grounds for lawsuits, it is not yet clear how these cases could change the playing field, as EPA already appears to be on its way to addressing existing legal deficiencies. The groups may be seeking a settlement with EPA or even an opportunity for EPA to request a remand of its Part 1 analysis. Notably, President Biden's nominee for EPA Administrator, Michael Regan, acknowledged during his confirmation hearing on February 3 that he would "work with [his] staff to take a look at [the asbestos] evaluation, determine where those data and science gaps are, and govern ourselves accordingly."

Implications
First, EPA is already conducting "Part 2" of its asbestos risk evaluation to address "legacy" asbestos in response to a previous court loss. A similar coalition of advocacy groups won their bid in the Ninth Circuit in November 2019 in which the court rejected EPA's argument that it had the authority to omit legacy asbestos from the scope of review. See Safer Chemicals Healthy Families, et al. v. EPA, No. 17-72260 (9th Cir. Nov. 14, 2019). EPA obviously could not complete the legacy analysis by June 2020 just 7 months following the Ninth Circuit's November 2019 order. However, the court's intervening decision does not alleviate EPA from the statutory deadline, making the agency legally vulnerable to a mandatory duty suit. While EPA is already conducting the review, the coalition may be looking to force a settlement—EPA's typical response when there is no legal defense. The groups may view this as more achievable with the new administration and as providing certainty on EPA's timeline and court oversight to ensure against slippage.

Second, the issue to watch is what problems the groups will allege with the Part 1 evaluation and the progress of

the litigation over the substance of the evaluation. Since Part 1 was completed in the prior administration, there is likely concern that allowing it to stand would leave in place a risk assessment that provides a less than desired foundation on which to craft risk management regulations. If the new administration chooses, it could even seek a voluntary remand of the action and merge Part 1 and Part 2. Additionally, legacy asbestos analysis has long been in the sights of advocacy groups and the deadline...

Significant Activity Follows US EPA's TSCA Asbestos Risk Evaluation
Gary L. Pasheilich, The National Law Review (Squire Patton Blogs)
https://www.natlawreview.com/article/significant-activity-follows-us-epa-s-tsca-asbestos-risk-evaluation

The US Environmental Protection Agency's (EPA's) December 30, 2020 issuance of its risk evaluation for asbestos under Section 6 of the Toxic Substances Control Act (TSCA) has generated considerable attention and activity, which will likely keep interested parties and the courts busy for quite some time.

As background, TSCA Section 6 requires EPA to prepare risk evaluations for "high priority" chemical substances that "may present an unreasonable risk of injury to health or the environment." Asbestos was selected as one of the "first ten" substances to undergo risk evaluation, as required by the 2016 TSCA amendments, without consideration of costs or other non-risk factors.

The processes for prioritizing and evaluating a chemical substance's risk to health and the environment were set forth in EPA's 2017 Risk Evaluation Rule, which requires evaluation of a chemical's "conditions of use," or "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." That rule was challenged and in late 2019, the Ninth Circuit Court of Appeals in Safer Chemicals, Healthy Families v. EPA, held that the rule could not exclude "legacy uses" (i.e., uses without ongoing or prospective manufacturing, processing, or distribution) or "associated disposals" (i.e., future disposal of legacy uses) from the risk evaluations.

In EPA's asbestos risk evaluation, it concluded (as in the March 30, 2020 draft) that: (1) there is no unreasonable risk to the environment under any of the conditions of use, but that (2) there is an unreasonable risk to workers, occupational non-users, consumers and bystanders under certain conditions of use. However, after considerable criticism from stakeholders and EPA's Science Advisory Committee on Chemicals (SACC), EPA characterized the risk evaluation as "Part 1" since it focuses only on chrysotile asbestos, which the agency determined is the only asbestos fiber type imported, processed, or distributed under the conditions of use in the United States. The other five fiber types included in TSCA's definition of asbestos are subject to an April 25, 2019 significant new use rule (SNUR). EPA has stated that it will conduct "Part 2" of the risk evaluation to address certain "legacy" uses and disposals of asbestos as required by the Ninth Circuit.

On January 26, a group of twelve environmental petitioners filed a Petition for Review with the Ninth Circuit challenging the Part 1 risk evaluation for its alleged failure to "consider the risks of other asbestos fibers, conditions of use, health effects and pathways of exposure that impact public health." Petitioners will also likely challenge EPA's finding in Part 1 that 16 of 32 conditions of use did not pose an unreasonable risk to workers, consumers and bystanders, and try to convince the Ninth Circuit to require EPA to reexamine those findings.

Moreover, the environmental groups have mounted a two-front attack on the risk evaluation by separately giving notice on January 26 of their intent to sue under TSCA Section 20, charging that EPA failed to perform its non-discretionary duty to address the use and disposal of legacy asbestos in the risk evaluation, as well as challenging EPA's lack of specifics about a future Part 2 evaluation and failure to set a schedule for completing it. Petitioners' Section 20 challenge would seek to impose a judicially-enforced deadline for evaluation of such legacy uses.

These legal challenges come on the heels of a December 22 decision from the Northern District Court of California, which held that EPA acted unlawfully in denying plaintiffs' TSCA Section 21 citizen petitions asking EPA to require companies importing or using asbestos to report such information on those uses to the TSCA program under the Chemical Data Reporting (CDR) rule. Finding that EPA's rationale was "arbitrary and....

The EPA Releases Supplement to its Draft Risk Evaluation for 1,4-Dioxane
N/A, Web Wire
https://www.webwire.com/ViewPressRel.asp?aId=270783

The U.S. Environmental Protection Agency (EPA) released a draft supplemental analysis last November to the agency's 2019 Draft Risk Evaluation for 1,4-Dioxane. In the supplemental analysis, the agency included eight consumer uses where 1,4-dioxane is present as a byproduct, meaning when 1,4-dioxane is created from the breakdown of other chemicals. It also now assesses exposure to the general population from 1,4-dioxane in surface water.

1,4-dioxane is a synthetic industrial chemical that also goes by other names such as dioxane, dioxan, p-dioxane, diethylene dioxide, diethylene oxide, diethylene ether and glycol ethylene ether. It easily dissolves in water and is used primarily as a solvent in the manufacture of other chemicals. The Agency for Toxic Substances & Disease Registry (ATSDR) also stated that it is a trace contaminant of some chemicals used in cosmetics, detergents and shampoos.

Exposure can harm the eyes, skin, lungs, liver and kidneys, and according to the EPA, 1,4-dioxane is a likely human carcinogen. The physical and chemical properties and behavior of 1,4-dioxane create challenges for its characterization and treatment. It is highly mobile, does not readily biodegrade in the environment and has been found in groundwater at sites throughout the United States.

"Exposure to 1,4-dioxane can cause risks as it is an industrial chemical that acts as a trace contaminant or byproduct in consumer goods, and is an environmental pollutant," said Joe Frasca, Senior Vice President of Marketing at EMSL Analytical, Inc. "At EMSL, our network of laboratories across the United States and Canada provide industrial hygiene and environmental testing for 1,4-dioxane and many other chemicals. These laboratory tests are available to regulatory agencies, manufacturers and environmental, health and safety professionals."

To learn more about chemical testing or other occupational, environmental, health and safety services, please visit www.EMSL.com, call (800) 220-3675 or email info@EMSL.com .

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And while you're reading…. Remember to shoot your coworkers a shooting star!